APR 17 2014

510(k) SUMMARY

AdvaLight ApS
ADVATx

510(k) Owner Name, Address, Telephone Number, Contact Person and Date Prepared

AdvaLight ApS
Brydehusvej 30
Ballerup DK-2750
Denmark
Phone: (+45) 2987 5863
Contact Person: Thomas Lund

Date Prepared: March 14, 2014

Common or Usual Name

Surgical Laser

Classification Name

21 C.F.R. 878.4810

Predicate Devices

Norseld Dual Yellow D10B (K032397)
Candela Vbeam (K043251)
Sciton Joule Multi-Platform System (K101916)
Cynosure TriStar Aesthetic Workstation (K033176)

Intended Use / Indications for Use

The ADVATx at 589nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea, cherry angiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne vulgaris, verrucae/warts, scars, striea, and psoriasis.

The ADVATx at 1319nm is indicated for treatment of fine lines and wrinkles. Treatment of atrophic acne scars. Treatment of mild and moderate inflammatory acne vulgaris.

Technological Characteristics

The ADVATx Laser System is a Nd:YAG laser delivering 589nm Q-switched pulsed light and 1319nm continuous wave light. This laser system was developed specifically for dermatological treatments. The laser light is delivered to the patient either through a scanner or a hand piece.

Performance Data

Electrical safety testing was performed which showed compliance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-22. Laser safety was evaluated and the ADVATx Laser System was found to comply with IEC 60825-1. System and software validation and verification demonstrate that the ADVATx performs as intended and meets its' specifications. Testing was performed which verified that the laser output spectrum and power are stable both over a single treatment session and long term.

Substantial Equivalence

The ADVATx 589nm wavelength is substantially equivalent to the Norseld Dual Yellow D10B Laser System (K032397) and the Candela Vbeam Laser System (K043251). The indications for use statement for the ADVATx for the 589nm wavelength is exactly the same as a subset of the indications for use statement for the Norseld Dual Yellow D10B Laser (K032397) and is very similar to the indications for use statement for the Candela Vbeam 595nm wavelength (K043251).

The ADVATx 589 nm wavelength and the predicate devices have the same technological characteristics. The ADVATx and the predicate devices are all stand-alone laser systems in the yellow spectrum that are used primarily for dermatological treatments. Treatment parameters including fluence, spot size, and pulse duration are all within the specifications of the previously cleared predicate devices. All of the devices (ADVATx, Norseld and Candela Vbeam) utilize a fiber connected to a hand piece to deliver the laser energy. Additionally, the ADVATx and the Norseld Dual Yellow D10B can be delivered with an optional scanner. The scanner treatment size for the ADVATx is 5 x 5 mm to 10 x 10 mm which is the same minimum and maximum scan area for the Norseld Dual Yellow D10B.

The ADVATx 1319nm wavelength is substantially equivalent to the Sciton Joule Laser System (K101916) and the Cynosure Tristar Laser System

(K033176). The indications for use statement for the ADVATx for the 1319nm wavelength is exactly the same as the indications for use statement for the Sciton Joule Multi-Platform System (K101916). The ADVATx 1319nm wavelength has the same intended use as the identified predicate devices and may be found to be substantially equivalent to the predicate devices.

The ADVATx 1319nm and the predicate devices are all Nd:YAG lasers with a wavelength of 1319nm wavelength (1320nm for the Cynosure predicate). All of the devices (from AdvaLight, Sciton and Cynosure) utilize a fiber connected to a hand piece to deliver the laser energy. Additionally, the ADVATx and the Sciton Joule Multi-Platform System are delivered using an optional scanner. The scanner treatment works on identical principles (single energy spots applied on the skin next to each other at very high speed filling out the complete area).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

AdvaLight ApS
% Ms. Maureen O'Connell
O'Connell Regulatory Consultants Incorporated
5 Timber Lane
North Reading, Massachusetts 01864

Re: K132976
Trade/Device Name: ADVATx
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 14, 2014
Received: March 18, 2014

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132976

Device Name
ADVATx

Indications for Use *(Describe)*
The ADVATx at 589 nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea, cherry angiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne vulgaris, verrucae/ warts, scars, striea, and psoriasis.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.04.17 13:54:56 -04'00'

For BSA

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